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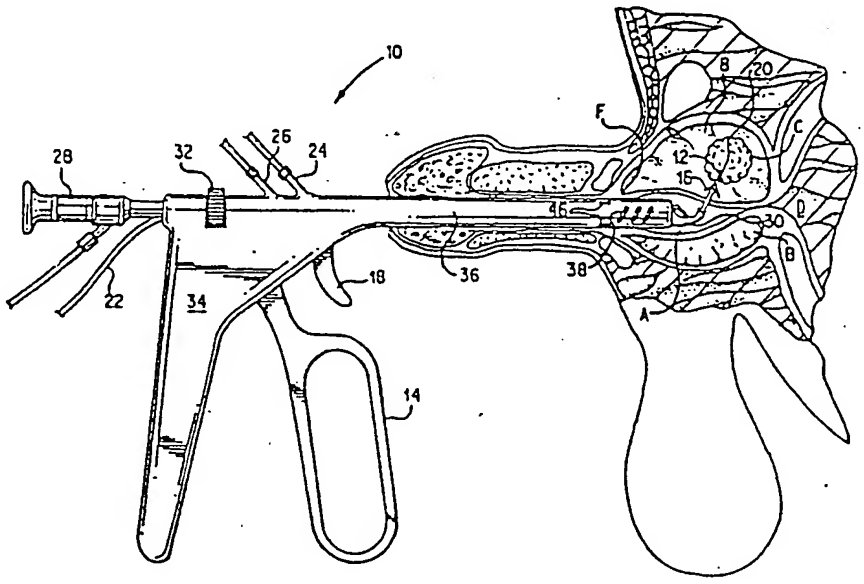

(57) Abstract

An apparatus and method for interstitial treatment and diagnosis in organs utilizing a flexible cannula (12) having an interstitial locking means (16) thereon. The apparatus includes a shaft for insertion into a body passage adjacent to the organ to be treated and adapted to guide cannula into the organ. The shaft is also adapted to receive an endoscope (28) to visualize insertion of the cannula. The cannula locking means includes a locking member which extends from the distal end of the cannula in response to relative motion between parts of the cannula.

APPARATUS AND METHOD FOR INTERSTITIAL TREATMENT

Related Application

The present application is a continuation-in-part of U.S. patent application No. 07/625,332, filed December 10, 1990.

Field of the Invention

The present invention relates to an apparatus and method for interstitial treatment or diagnosis in organs, in particular, by insertion of an elongated shaft of the apparatus into a body passage adjacent the organ to be treated and extension of a cannula into the organ for delivery of treatment or diagnosis at a selected site within the organ. More particularly, the cannula includes an interstitial locking means for reversibly locking the cannula in place after positioning and during treatment.

Background of the Invention

Advances in medical technology have provided many new treatments and diagnostic techniques. For example, U.S. Patent No. 4,950,267 to Ishihara et al. discloses a laser beam treatment device for an endoscope. The endoscope delivers a laser probe to a position in a body, from which the laser probe is thrust into the part of the organ to be treated. However, the disclosure is not too specific as how the laser probe is inserted into the organ. Also, U.S. Patent No. 5,047,026 to Rydel discloses an electrosurgical implant for cutting through tissue. The instrument includes two separate terminals at the distal end that provide an arc discharge when a RF voltage is applied, thereby allowing the device to cut tissue. No provision, however, is made for transporting the distal end to a particular treatment site with minimal damage to healthy tissue surrounding the treatment site.

Other treatment techniques include the implantation of radioactive seeds for radiation therapy or interstitially cell-targeted drug therapies. Also, many different types of diagnostic techniques are known, such as endoscopic or ultrasound visualization. However, suitable apparatus and methods for applying these techniques interstitially are lacking in the art

Thus, despite the numerous advances and new techniques developed for medical treatment and diagnosis, there remains in the art a need for a suitable apparatus and method to interstitially deliver such treatments to or conduct diagnosis at selected sites within an organ, without excessive and unnecessary damage to tissue surrounding the treatment site.

Summary of the Invention

It is therefore an object of the present invention to provide a method and apparatus for interstitially delivering various treatments or diagnoses to selected sites within an organ.

It is a further object of the invention to provide such an apparatus which can be easily and accurately manipulated by an operator to direct treatment or diagnosis to the desired interstitial location with minimal damage to surrounding tissue.

Another object of the present invention is to provide means for securing a cannula interstitially within an organ to ensure that treatment delivery or diagnosis occurs at the selected site without the necessity of constantly monitoring the position the cannula.

These and other objects are realized according to the invention by an apparatus for interstitial treatment or diagnosis in an organ which includes an elongated, and at least partially flexible

cannula, means for positioning the cannula in a body passage adjacent to the organ to be treated, a guide means mounted on the positioning means to guide the cannula into the organ, and means for locking the cannula in place during treatment or diagnosis. The apparatus further includes a proximal portion that supports the positioning means for manipulation and allows the positioning means to be rotated in order to position the guide means for directing the cannula into the organ at a predetermined location.

A preferred embodiment of the invention further includes a support structure with a distally extending shaft portion that surrounds the positioning means. In this embodiment of the apparatus, a moveable assembly is mounted into the support structure to cooperate with the positioning means and rotate the positioning means and guide means in response to its own rotation. The proximal end of the cannula is also secured to the moveable assembly such that axial translation of the moveable assembly causes the cannula to translate with respect to the positioning means, thus, allowing the cannula to be inserted into the organ.

According to the further embodiment of the invention, the cannula comprises an outer member and an inner member received within the outer member. The locking means includes a locking member secured to the inner member adjacent to the distal end and disposed substantially between the inner and outer members. The locking member is arranged such that it is capable of movement from a first non-locking position between the inner and outer members to a second locking position extending into the tissue surrounding the cannula. Such movement is in response to relative movement between the inner and outer members. The moveable assembly includes a body member secured to the outer cannula member and a support member secured

to the inner cannula member such that relative movement between the body member and support member effects the movement of the locking member from the first to second positions.

In order to allow an operator to manipulate the apparatus with a single hand, the apparatus further includes a handle member mounted on the support structure cooperating with the body member of the moveable assembly, whereby squeezing the handle member causes translation of the moveable assembly with respect to the support structure in order to advance the cannula into the organ. The apparatus further includes a trigger member also mounted on the support structure and cooperating with the support member such that depressing the trigger member moves the support member separately from the body member to move the locking member from the first position to the second position. Additionally, a wheel means such as a thumb wheel is provided on the body member to allow ease of rotation of the body member for positioning the guide means.

In a preferred embodiment of the present invention, the locking cannula includes an outer member that comprises a hollow flexible needle defining a radial opening adjacent to its distal end. The inner member comprises an energy delivery means disposed within the needle. The locking member secured to the energy delivery means such that relative motion between the needle and energy delivery means causes the locking member to move from the first non-locking position to the second locking position extending into surrounding tissue.

In a further preferred embodiment, the inner member of the locking cannula comprises a hollow inner sheath with the locking member disposed thereon. The outer member also comprises a hollow sheath which defines a radial opening adjacent to its distal end.

The locking member and the opening are arranged such that relative movement between the sheaths moves the locking member through the opening from the first non-locking position to the second locked position. According to further details of the invention, the inner sheath may comprise a helically wound construction and have a separate distal tip portion which defines a recess that receives the locking member in the first position. In energy delivery embodiments of the invention, the distal tip is preferably a heat resistent and non-conductive material.

The present invention also includes a kit for interstitial treatment or diagnosis in an organ including a locking cannula substantially as described above and an apparatus generally as described above, and, further, an endoscope configured and dimensioned to be inserted into the apparatus to allow for visualizing the insertion of the cannula into the organ. The kit, according to the invention, may also include an obturator adapted to be inserted into the apparatus to facilitate positioning of the apparatus in the body passage. The kit may also include a stylet adapted to be received in the cannula and extend distally beyond the cannula in order to facilitate insertion of the cannula into the organ. A further component of the kit is an energy source having a means for delivering energy configured and dimensioned to be received within the cannula and extend beyond the distal end of the cannula for delivery of energy to the organ. Energy sources included with the kit, include sources of microwave energy, ultrasound energy, laser energy, radiofrequency energy and thermal energy. In order to deliver these various types of energy, the kit includes energy delivery means such as an antenna,

optical fiber, wire, bipole device or piezoelectric element.

The present invention also includes a method for interstitial treatment or diagnosis within an organ. According to the method, a tubular member is placed within the body passage adjacent to the organ to be treated. A cannula is guided into the organ by the tubular member with the cannula puncturing the tissue of the organ. The cannula is located with its distal end at a treatment zone within the organ. The cannula is locked in the organ and treatment or diagnosis is performed at the zone.

The method according to the invention includes a multi-step treatment method wherein the cannula is guided and inserted into the organ by placing a stylet within the cannula and advancing both the cannula and the stylet together into the organ. After the cannula is located at the treatment zone and locked in place, the stylet is withdrawn and a cell targeted compound sensitive to an energy type is interstitially applied to the organ through the cannula. The particular type of energy is then applied through the cannula to the targeted cells.

Brief Description of the Drawing

FIG. 1 is a view of the median sagittal section of the male pelvis illustrating the use of one embodiment of the apparatus according to the present invention for treating the prostate;

FIGS. 2-5 are a sequence of enlarged cross-sectional views of the prostate, illustrating the steps of one embodiment the method of the present invention, utilizing the apparatus shown in FIG. 1;

FIG. 6 is a schematic, partial section view of the apparatus shown in FIG. 1, illustrating a mechanism for positioning, advancing and locking the cannula according to one embodiment of the invention;

FIG. 7 is an end view of the guide wheel shown with the apparatus in FIGS. 1 and 6;

FIG. 8 is an enlarged, partial section view of the apparatus shown in FIG. 6;

FIG. 9 is an enlarged section view of the distal end of the locking cannula shown in FIG. 1, with a barb locking means according to the present invention in the retracted position;

FIG. 10 is a section view of the barb locking means shown in FIG. 9 in the extended and locked position;

FIG. 11 is a side view of the distal end of an alternative embodiment of the apparatus of the invention, similar to the apparatus shown in FIG. 1 with an extended shaft;

FIG. 12 illustrates a further alternative embodiment of the apparatus according to the invention;

FIGS. 13 and 14 illustrate an obturator and stylet, respectively, for use with the apparatus shown in FIG. 12;

FIG. 15 is a section view of the distal end of the locking cannula of the apparatus of FIG. 12, with a barb locking in the retracted position and the stylet in place;

FIG. 16 is a section view of the barb locking means shown in FIG. 15 in the extended and locked position, with an energy delivery means in place;

FIG. 17 is a section view of the distal end of an alternative locking cannula;

FIG. 18 is a section view of the distal end of the alternative locking cannula shown in FIG. 17, with an energy delivery means in place; and

FIG. 19 is a section view of a further alternative embodiment of the locking cannula according to the present invention.

Detailed Description of the Preferred Embodiments

In order to provide an overall understanding of the present invention, the method of the invention will be discussed with reference to laser ablation treatment of benign prostatic hypertrophy (BPH). However, it will be understood by persons of ordinary skill in the art that the general method and apparatus as described herein are equally applicable treatment of any organ which is accessible through a body passage similar to the accessibility of the prostate by the urethra. For example, the prostate could be approached rectally or peritoneally by laparoscopic techniques, as could other organs. Also, numerous treatments other than laser ablation are possible with the present invention.

Referring first to FIG. 1, an interstitial treatment delivery apparatus 10 according to the invention is positioned in the prostatic urethra A with its distal end adjacent to the prostate B. Locking cannula 12 has been extended by squeezing hand lever 14 and the interstitial locking means 16 deployed by depressing trigger 18. Laser energy has been or is being delivered to treatment area C by sharpened tip 20 of laser fiber 22. An Nd:YAG or diode laser provides a suitable laser energy source. A tuneable dye laser also may be used depending on the particular application. Persons of ordinary skill in the art could identify other laser sources and select suitable optical fibers for use therewith. Other components of apparatus 10 shown in FIG. 1, whose function and interrelationship will be explained in detail below, are fluid ports 24 and 26, endoscope 28, cannula guide 30, guide wheel 32, hand piece 34 and shaft 36.

After insertion of endoscope 28 into hand piece 34, shaft 36 is advanced into the prostatic urethra A while visualizing the verumontanum, as

indicated by arrow 37 in FIG. 2. A dilation fluid may be introduced through one of ports 24 or 26 which communicate with distal openings 38 to facilitate introduction of the shaft. The dilation fluid can be removed through the other of ports 24 or 26, or be allowed temporarily to accumulate in the bladder D. By rotating guide wheel 32, cannula guide 30 is directed toward the wall of the urethra corresponding to the treatment zone E. Arrow 39 indicates the movement of cannula guide 30. Positioning of shaft 36 and cannula guide 30 is viewed through endoscope 28 and endoscope port 40.

Referring to FIGS. 3 and 4, as handle lever 14 is squeezed, locking cannula 12, with sharpened fiber tip 20, is exposed and directed through the urethral wall toward treatment zone E. The sharpened tip facilitates puncturing the urethral wall and pushing the cannula through the prostate. However, a sharpened laser fiber is not required. For example, as explained below, a stylet may be used for insertion of the cannula into the organ and subsequently a laser fiber (or other energy delivery means) with any desired tip may replace the stylet for treatment.

The depth of insertion into the prostate B can be determined by viewing contrasting markings 42 on the outside of cannula 12. Such contrasting markings can be on the outer surface of the cannula, for example as impregnate plastic rings, or located on an inner surface, visualizable through the cannula outer surface. Other markings are possible, the primary requirement being the ability to be readily visualized on the cannula outer surface.

As the distal end of the locking cannula approaches the treatment zone E, ultrasound is used to finely position tip 20 for treatment. The ultrasound may be applied, for example, with a transrectal ultrasound probe or by removing endoscope 28 and

inserting a transurethral ultrasound probe through shaft 36. Preferably cannula 12 is provided with an echogenic construction or surface treatment to improve contrast and facilitate ultrasound visualization.

Once tip 20 is in the desired position for treatment, locking means 16 are deployed as shown in FIG. 5, to positively lock the cannula in place during treatment. Locking means 16 are deployed by depressing trigger 18, which causes a coaxial movement that extends barbs or other means. The various alternative configurations of locking means are described below in greater detail.

Referring again to FIG. 1, laser energy is shown applied through sharpened tip 20 to treat the prostate. With a sharpened tip, the area of treatment is generally spherical, with the tip located approximately at the center of the sphere.

During application of laser energy, it is necessary to monitor the temperature of surrounding tissue in order to prevent unwanted tissue damage. For this purpose, temperature sensing devices 46, such as thermocouples or miniaturized thermistors, are placed in appropriate locations along shaft 36, and also on cannula 12 as explained below. A person of ordinary skill in the art would have sufficient knowledge to provide the necessary connections to monitoring devices and the exact locations for the sensing devices.

In high temperature energy delivery systems it is desirable to cool portions of the anatomy to prevent damage by overheating. For example, cooling fluid may be introduced through ports 24 or 26 to cool shaft 36 in the region of the external sphincter F. Damage to the external sphincter could cause incontinence. It also may be desirable to extend shaft 36 distally, as shown in FIG. 11, in order to provide direct cooling to the bladder neck area G.

The cooling fluid may be circulated in and out of ports 24 and 26, or it may exit openings 38 and temporarily accumulate in the bladder. Accumulation in the bladder would also allow a degree of cooling of the bladder neck without a shaft extending therebetween.

After treatment, the locking means is retracted and the cannula removed. Alternatively, the cannula may be repositioned and the locking means redeployed for further treatment.

Turning now to FIGS. 6-19, wherein like reference numerals refer to like parts, the details of the various alternative embodiments of the present invention may be described in greater detail. FIG. 6 schematically illustrates the operating mechanism of apparatus 10, shown in FIG. 1. Apparatus 10 generally comprises a moveable assembly 48 and barrel 50 contained within support structure 52. Support structure 52 includes shaft portion 36 and hand piece 34. Moveable assembly 48 is mounted for both rotation and axial movement, whereas barrel 50 is constrained against axial movement but does rotate with moveable assembly 48. In addition to supporting the moveable assembly and barrel, support structure 52 provides passages for flow of fluids between ports 24 and 26, and openings 38. The specific arrangement of such passages is within the skill of an ordinary skilled worker in the art and therefore they have been omitted from the drawing for reasons of clarity.

Hand piece 34 is constructed of a suitable rigid material such as stainless steel or plastic in order to support moveable assembly 48 and allow for manipulation by hand.

Depending on the particular application and other factors determined by the operator, shaft portion 36 can take a variety of forms. For example, it may be rigid, flexible, malleable, articulatable or

expandable. Flexible embodiments may be constructed similar to known catheters. By providing controllable joints, articulatable embodiments would be well suited for manipulation within the peritoneum. Expandable embodiments include longitudinal expansion by telescoping shafts and radial expansion, for example, by balloon structures on the shaft. U.S. patent application No. 07/625,332, filed December 10, 1990, which is incorporated herein by reference thereto, discloses a number of shaft balloon configurations suitable for use in the shaft portion of the present invention. Balloon expandable shafts provide a locking feature in addition to the locking cannula described herein and, thus, provide increased confidence in the accuracy of treatment application. Shaft balloons can also be inflated using a cooling or heat transfer medium in order to cool the body passage and surrounding tissue during energy delivery.

Moveable assembly 48 is rotated by rotating guide wheel 54. This also causes barrel 50 to rotate, which positions cannula guide 30 as described above. Any suitable means for directing the cannula may serve as cannula guide 30. A preferred embodiment includes a member defining a curved passage through which the cannula slides. The moveable assembly is advanced by squeezing handle lever 14. When moved in the direction of arrow 56, the handle lever pivots at point 58 (mounted on support structure 52) and moves cam member 60 forward. Cam member 60 engages lever ring 62 to cause axial movement of the moveable assembly. Lever ring 62 is fixed to moveable assembly 48. Notch 64 in cam member 60 allows lever ring 62 to rotate when the guide wheel is rotated, while at the same time constantly engaging ring 62 for axial adjustment. Guide wheel 54 (FIG. 7) has an internal key 66 that cooperates with slot 68 in moveable assembly 48 to allow rotational engagement and free

axial movement of the guide wheel with respect to the moveable assembly.

Trigger 18 is slideably mounted on support structure 52. Trigger arm 70 includes notch 72 that cooperates with trigger ring 76 in the same manner as notch 64 and lever ring 62. However, trigger ring 76 is not fixed to moveable assembly 48. Trigger ring 76 moves with the moveable assembly so long as trigger 18 is not depressed. When the trigger is depressed, trigger ring 76 moves to the left as shown in FIG. 6, independent of moveable assembly 48.

As shown in FIG. 8, cannula 12 comprises inner sheath 80 and outer sheath 82. An energy delivery means, in this case laser fiber 22, is contained within inner sheath 80. The cannula and laser fiber are not shown in section. The cannula is generally flexible to allow it to be guided by cannula guide 30 and for ease of insertion into the organ. Also, being flexible, cannula 12 is well suited for use of a steering fiber as disclosed in co-pending application No. 07/625,332 in order to provide a cannula that is steerable within the organ. In certain applications, it may be desirable to provide a rigid tip portion to facilitate insertion or increase insulative characteristics as discussed below, or to provide a rigid proximal shaft portion to enhance manipulation of the cannula. As understood by a person skilled in the art, such rigid portions can be provided without compromising the general flexibility of the cannula.

Also shown in FIG. 8 is endoscope channel 81 and rotary uniting rod 83. The rotary uniting rod ensures that barrel 50 rotates with moveable assembly 48, but is received in a hole to allow the moveable assembly to translate without translation of the barrel.

Trigger ring 76 has a forward extending, inner sheath support member 84. The support member is hollow to define a passage for the laser fiber and is secured to inner sheath 80 at joint 86. Inner sheath support member 84 is slideably received in outer sheath support member 88. The outer sheath support member extends from body 90 of the moveable assembly and is connected to outer sheath 82 at joint 92. Therefore, when lever ring 62 is advanced as explained above, outer sheath 82 moves forward and, as long as trigger 18 is not depressed, the inner sheath and laser fiber move with it to extend cannula 12 into the prostate or other organ to be treated.

Once the cannula is positioned for treatment, locking means 16 is deployed. This is accomplished by depressing trigger 18 which, through the cooperation of the elements as explained, causes inner sheath 80 to move back or proximally. Trigger ring 76 is shown in a partially depressed position in FIG. 8.

Deployment of locking means 16 according to the embodiment shown in FIG. 1 may be explained in greater detail by reference to FIGS. 9 and 10. FIG. 1 shows the use of multiple locking members, however, a single locking member is shown in FIGS. 9 and 10 for clarity. FIG. 9 illustrates the distal end of the cannula as it is extended into the organ. Sharpened laser fiber tip 20 forms the piercing tip of the cannula. As discussed below, other structures such as a separate stylet or hollow needle may serve this purpose. Preferably, the inner and outer sheaths are tapered at the distal end to form a profile that facilitates insertion.

Inner sheath 80 includes a shaft portion 96 that is constructed from helically wound wire, similar to known guide wires, in order to combine sufficient axial stiffness and pushability with bendability. At

the distal end of inner sheath 80, a tip 98 is provided that carries locking barb 100 in recess 102. Barb 100 can be made of any biocompatible material having sufficient strength, hardness and elasticity to be inserted and withdrawn from the surrounding tissue a number of times without failure. Such materials include stainless, carbonized or anodized steel, nitinol and various hard plastics. The end of locking barb 100 is aligned with opening 104 in outer sheath 82. When inner sheath 80 is moved back as described above, locking barb 100 exits opening 104 to become implanted in the organ as shown in FIG. 10. With the locking barb extended, the distal end of cannula 12 is secured adjacent to the treatment site. The operator may then release his or her grip on apparatus 10 in order to concentrate on the treatment, without the need to manually maintain the laser fiber or other treatment means in place.

Locking means 16 is retracted or reversed by moving trigger ring 76 in the opposite direction from that used to deploy the locking means. This can be accomplished manually or automatically. One means (not shown) for automatic retraction is to provide a spring mechanism which can be locked by the operator and, when released, biases trigger ring 76 to the retracted position.

For energy delivery treatments that involve high temperature, such as laser ablation, it is preferable that tip 98 be made of a non-heat conductive material in order to prevent heat transfer to shaft portion 98. In order to monitor energy delivery and temperature, temperature sensing devices 46 are located along laser fiber 22 and cannula 12. In addition to thermocouples or thermistors as explained above, temperature sensing can be accomplished by fiber optic temperature sensors or infrared measuring along the cannula. Also,

ultrasound may be used to measure temperature remotely by tissue characterization through signal processing of the ultrasound image. The amount of tissue damage can also be determined by sensing NADPH, a compound produced by cell death.

Depending on the type of treatment which is to be delivered, the construction and materials for outer sheath 82 (also inner sheath 80) will vary. For high temperature energy delivery systems materials capable of withstanding the high temperatures must be used. The outer sheath also must be made of an insulating or nonconductive material to prevent heat transfer down its shaft. One advantage of the present invention is that by delivering the cannula through a relatively small puncture wound, the hole heals quickly and with minimal chance for infection after treatment. If heat transfer down the outer sheath is sufficient to cauterize the surrounding tissue, a more permanent and difficult to heal hole can be created. Also, similar to the inner sheath, the outer sheath must be axially stiff but bendable, although the stiffness may be provided by a guide wire-like construction of the inner sheath. As an alternative, the outer and inner sheaths can be two or more parts, with the tapered distal portion being a relatively stiff and highly nonconductive material such as ceramic. Persons skilled in the art can identify suitable materials, such as teflon, silicon, polyurethane, polymers and copolymers, which will meet the requirements for the particular application.

To assist in ultrasound positioning, the cannula can be provided with an echogenic construction. This may result as a function of the different materials chosen for the inner and outer sheaths, or can be intentionally created, for example, by forming the cannula with two different materials having different acoustical impedances and interfacing

non-uniformly to create multiple angles of reflectance.

In certain applications it may be desirable to create a more permanent hole, for example for drainage, or to otherwise cauterize the surrounding tissue. In such instances the sheaths may be constructed of highly conductive material such that energy delivery at the tip is transferred down along the outer sheaths. Alternatively, and in particular in non-energy delivery applications, it may be desirable to provide the cannula itself with a heat source for cauterization. For example, electric resistance heating could be used for this purpose.

Turning now to FIG. 11, there is shown an alternative embodiment of apparatus 10 having an extended shaft portion 106. An opening 108 is provided in the shaft to allow cannula guide 30 and endoscope port 40 to access the urethral wall. Otherwise the construction and operation of the apparatus is substantially the same as described above. Extended shaft portion 106 is especially well suited for use of a tip balloon as disclosed in co-pending U.S. application No. 07/625,332. The extended shaft can also be of sufficient length to be disposed within the bladder neck G during energy delivery in order to provide a direct cooling source thereto.

FIG. 12 illustrates a further alternative embodiment of the present invention. In FIG. 12, apparatus 110 is shown substantially as it would appear in place for energy delivery treatment to an organ. An introducer assembly 112 includes shaft 114, which generally corresponds to shaft 36 in apparatus 10. A preferred configuration of shaft 114 is a 21-22 french stainless steel cannula, although alternatives such as those explained above in connection with apparatus 10 are also possible. Endoscope 116 is shown inserted into the introducer assembly.

Irrigation and light source connections 118 and 120, respectively, are also provided. The distal end of shaft 114 provides an endoscope port and forms a cannula guide 122. The direction of insertion of cannula 12 thus may be controlled by turning the introducer assembly.

Locking cannula 12 enters introducer assembly 112 through port 126 and extends out of cannula guide 122. Locking actuator 130 provides coaxial movement between outer sheath 82 and inner sheath 80 (shown in detail in FIGS. 15 and 16). An energy delivery means 136 is inserted into the cannula through port 138 in locking actuator 130.

In use, the introducer assembly would first be fitted with obturator 140, shown in FIG. 13. At this point neither the endoscope nor the cannula would be placed in the introducer assembly. The operator would then insert introducer assembly 112, with obturator 140, into the urethra in a similar manner to the insertion of a cystoscope. Again, as with apparatus 10, the urethra and prostate are used as a reference for descriptive purposes only and not as a limitation of the invention.

After the distal end of shaft 114 is in the vicinity of the prostate or other targeted organ, obturator 140 is removed and endoscope 116 is inserted with appropriate connections to the light source and irrigation. Stylet 142 is inserted into cannula 12, through port 138. Stylet 142 is shown in FIGS. 14 and 15. Cannula 12 is then inserted into the introducer assembly through port 126 until it extends from cannula guide 122 and is visible through the endoscope. The introducer assembly is rotated to position the cannula in the direction of the treatment zone. Cannula 12 is then extended into the prostate by gripping its proximal end and pushing or by pushing on actuator 130 to force stylet 142 into the prostate.

Contrasting markings 42 on cannula 12 can be viewed through the endoscope and also with the naked eye at port 126. Final positioning for treatment is again accomplished by ultrasound.

After the treatment zone is reached, inner sheath 80 is retracted using finger grips 146 and 148 of anchor actuator 130. Locking means 16 is thereby deployed as previously described. As shown in FIG. 16, once the distal end of cannula 12 is locked in place, stylet 142 is removed and energy delivery means 136 is inserted to extend a predetermined distance distally out of the cannula. The amount of extension can be determined visually by markings or by a mechanical stop.

FIGS. 17 and 18 illustrate another alternative embodiment of the present invention. In this embodiment, the coaxial movement of inner sheath 80 and outer sheath 82 is reversed from that shown in FIGS. 15 and 16. As the treatment zone is approached, inner sheath 80 is extended forward to the final position. This action causes barb 150 to extend out of opening 152 and lock the distal end of the cannula in place. In order to assume its hook-like shape, it is preferred that barb 150 be made of a material with a good elastic memory, such as nitinol. After the barb is extended, stylet 142 may be withdrawn and energy delivery means 136 inserted in its place.

Energy delivery means 136 need not be a laser fiber. Other energy delivery systems which will produce the desired effect on the tissue may be used. For example, for ablation, means 136 could comprise a microwave antenna, an ultrasound probe (either a wire leading to a remote source or a piezoelectric apparatus at the distal location), a radio frequency source such as a bipole located at the tip, or other thermal energy systems such as electrical resistance.

Due to the capability of removing the energy delivery means without removing the apparatus as whole, the present invention is particularly well suited for multiple step therapies. For example, a photodynamic therapy may be applied using a compound which is specifically targeted to particular cells and sensitive to selected light frequencies. Such targeting can be achieved by linking the compound to monoclonal antibodies having an affinity for the target cells. The compound would be applied through cannula 12 and allowed sufficient time to reach the target cells. An optical fiber would then be inserted into cannula 12 to apply laser or other appropriate light for treatment. The interstitial locking means 16 ensures that the light energy is applied at the same location as was the compound.

It is also not required that an energy delivery system be used at all. After cannula 12 is locked in place by locking means 16, and stylet 142 is removed, the cannula provides an ideal conduit for other treatments such as interstitially targeted drug therapy, radiation treatment by implantation of radioactive "seeds", or implantation of microwave "seeds" (essentially small metal strips) for subsequent application of microwave energy. Cannula 12 also may be used for aspiration or irrigation directly at a treatment site.

Additionally, cannula 12 can be used for diagnostic purposes as well as therapeutic. For example, the probe of an endoscope or ultrasound imager may be directed to a specific location in an organ. Contrast agents could be delivered to improve external radiographic, magnetic resonance or ultrasound imaging.

It is not required that cannula 12 have coaxial sheaths. FIG. 19 shows a further embodiment of the invention utilizing flexible needle 154 as an

outer member and energy delivery means 136 to deploy locking barb 156. Locking barb 156 is secured to delivery means 136 by collar 158 and received in recess 160 in needle 154 when retracted. In use, needle 154 is inserted into the organ, to the treatment location, by suitable means as described herein. The needle is then slightly backed off and means 136 separately advanced into the treatment position, simultaneously deploying barb 156 through curved guide hole 162. Means 136 may have a tapered or sharpened end to facilitate its advancement into the passage created by the needle. This embodiment is particularly well suited for application with the flexible and steerable needles and apparatus disclosed in U.S. application No. 07/625,332, which has been incorporated by reference.

Claims

1. An apparatus for interstitial treatment or diagnosis in an organ, comprising:

an elongated and at least partially flexible cannula having a distal end for insertion into the organ and a proximal end;

means for positioning the cannula in a body passage adjacent the organ, said positioning means having proximal and distal ends;

means for guiding the cannula into the organ mounted on said positioning means; and

means for locking the cannula in place during treatment or diagnosis.

2. The apparatus according to claim 1, wherein said cannula locking means is disposed on the cannula adjacent to the distal end.

3. The apparatus according to claim 1, wherein said positioning means defines a passageway for receiving an endoscope and an endoscope port disposed to allow viewing of insertion of the cannula into the organ.

4. The apparatus according to claim 3, further comprising contrasting markings visualizable on the cannula outer surface, whereby the distance of insertion of the cannula into the organ may be viewed through the endoscope.

5. The apparatus according to claim 3, further comprising a proximal portion supporting said positioning means at the proximal end thereof and providing means for manipulating said positioning means wherein said positioning means may be rotated to

position the guide means for guiding the cannula into the organ at a predetermined location.

6. The apparatus according to claim 5, further comprising at least one fluid port mounted on the proximal portion and at least one fluid passage in said apparatus communicating with the fluid port to circulate cooling fluid such that tissue surrounding said positioning means may be cooled at predetermined locations.

7. The apparatus according to claim 5, wherein said guide means comprises a member mounted at the distal end of said positioning means, said member defining a curved passage configured and dimensioned to receive the cannula for axial sliding movement.

8. The apparatus according to claim 5, wherein:

the cannula comprises an outer member and an inner member received within the outer member for axial movement therebetween, the cannula being removable from and axially insertable into said positioning means and proximal portion;

said locking means comprises a locking member secured to the inner member and capable of movement between a first non-locking position substantially between the inner member and the outer member, and a second locking position extending into tissue surrounding the cannula in response to relative movement between the inner and outer members; and

the apparatus includes means at the proximal end of the cannula for actuating the locking means comprising a first member secured to the outer cannula member and a second member secured to inner cannula member, whereby movement of said first member relative to said second member moves the locking

member from the first position to the second position.

9. The apparatus according to claim 5, wherein said proximal portion comprises a support structure having a distally extending shaft portion surrounding said positioning means.

10. The apparatus according to claim 9, further comprising a moveable assembly mounted in the support structure for rotation and axial translation, said moveable assembly cooperating with the positioning means to rotate the positioning means and guide means in response to rotation of the moveable assembly wherein the proximal end of the cannula is secured to the moveable assembly such that axial translation of the moveable assembly translates the cannula with respect to the positioning means, whereby the cannula may be inserted into the organ.

11. The apparatus according to claim 10, wherein:

the cannula comprises an outer member and an inner member received within the outer member for axial movement therebetween;

said locking means comprises a locking member secured to the inner member adjacent the distal end and capable of movement between a first non-locking position substantially between the inner member and the outer member, and a second locking position extending into tissue surrounding the cannula in response to relative movement between the inner and outer members; and

the moveable assembly comprises a body member with the outer member secured thereto and a support member for the cannula inner member at least partially received within the body member and secured

to the inner member, said inner member support member capable of movement both with and separate from the body member.

12. The apparatus according to claim 11, further comprising:

a handle member mounted on the support structure and cooperating with the body member whereby movement of said handle member causes translation of the moveable assembly with respect to the support structure;

a trigger member mounted on the support structure and cooperating with the inner member support member whereby movement of said trigger member causes the inner member support member to move separately from the body member to move the locking member from the first position to the second position; and

wheel means engaging the body member for rotation whereby rotation of said wheel means positions said guide means.

13. The apparatus according to claim 12, wherein said handle member, said trigger member and said wheel means are arranged to be manipulated by a single hand of an operator.

14. The apparatus according to claim 1, wherein said cannula locking means is disposed on the cannula and includes a locking member capable of movement between a first non-locking position and a second locking position extending into tissue surrounding the cannula.

15. The apparatus according to claim 14, wherein:

the cannula comprises a hollow, flexible needle defining a radial opening adjacent the distal end;

said apparatus further comprises means for energy delivery to the organ disposed within the needle; and

the locking member is secured to the energy delivery means such that it is disposed substantially between needle and said delivery means in the first position and relative movement between the needle and said delivery means moves the locking member through said opening to the second position.

16. The apparatus according to claim 14, wherein the cannula comprises:

an inner sheath with the cannula locking member disposed thereon; and

an outer sheath defining a radial opening;

the locking member and opening being arranged such that the locking member is disposed substantially between said sheaths in the first position and relative movement between the sheaths moves the locking member through said opening to the second position.

17. The apparatus according to claim 16, further comprising:

means for energy delivery to the organ disposed within the cannula; and

means for sensing the temperature of energy delivery, including sensing means disposed on the cannula.

18. The apparatus according to claim 17, wherein temperature sensing means are disposed on said

positioning means and the apparatus includes means for cooling tissue surrounding said positioning means.

19. The apparatus according to claim 17, wherein said energy delivery means includes a sharpened distal tip extending distally beyond the cannula to facilitate insertion into the organ.

20. The apparatus according to claim 14, further comprising means for advancing the cannula into the organ and means for actuating said locking means, said advancing and actuating means being capable of manipulation by one hand of the operator.

21. The apparatus according to claim 14, further comprising at least one inflatable balloon surrounding said positioning means and means for inflating the balloon to secure the positioning means in the body passage.

22. A kit for interstitial treatment or diagnosis in an organ, comprising:

a cannula having a distal end for insertion into the organ, a proximal end and means for locking the cannula in the organ;

an apparatus having means for positioning the cannula in a body passage adjacent the organ and having means for guiding the cannula into the organ; and

an endoscope configured and dimensioned to be inserted into the positioning means for visualizing insertion of the cannula into the organ.

23. The kit according to claim 22, wherein said cannula locking means includes a locking member capable of movement between a first non-locking

position and a second locking position extending into tissue surrounding the cannula.

24. The kit according to claim 23, further comprising means for advancing the cannula into the organ and means for actuating the locking means, said advancing and actuating means being capable of manipulation by one hand of the operator.

25. The kit according to claim 24, further comprising an obturator adapted to be inserted into said positioning means for facilitating positioning of said positioning means in the body passage.

26. The kit according to claim 24, further comprising a removable stylet adapted to be received in the cannula and extend distally beyond the cannula to facilitate insertion of the cannula into the organ.

27. The kit according to claim 24, further comprising an energy source with means for delivering energy configured and dimensioned to be received in the cannula for energy delivery to the organ at the distal end of the cannula.

28. The kit according to claim 27, wherein said energy source provides microwave, ultrasound, laser, radio frequency or thermal energy.

29. The kit according to claim 28, wherein said energy delivery means is an antenna, optical fiber, wire, bipole device or piezoelectric element.

30. A locking cannula for interstitial delivery of treatment or diagnosis in an organ, comprising:

an elongated outer member;

an elongated inner member received within the outer member for axial movement therebetween, said members each having a distal end for insertion into the organ and a proximal end for manipulation; and

a locking member secured to the inner member adjacent the distal end and capable of movement between a first non-locking position substantially between the inner member and the outer member, and a second locking position extending into tissue surrounding the cannula in response to relative movement between the inner and outer members.

31. The cannula according to claim 30, wherein:

the outer member comprises a hollow, flexible needle defining a radial opening adjacent the distal end;

the inner member comprises means for delivering energy disposed within the needle; and

the locking member is secured to the energy delivery means such that it is disposed substantially between needle and said delivery means in the first position, and relative movement between the needle and said delivery means moves the locking member through said opening to the second position.

32. The cannula according to claim 31, wherein:

the inner member comprises a hollow inner sheath with the locking member disposed thereon;

the outer member comprises a hollow outer sheath defining a radial opening adjacent the distal end; and

the locking member and opening are arranged such that relative movement between the

sheaths moves the locking member through said opening from the first position to the second position.

33. The cannula according to claim 32, wherein the inner sheath includes a shaft portion comprising a helically wound wire construction and a distal tip portion defining a recess for receiving the locking member in the first position.

34. The cannula according to claim 33, wherein the distal tip portion is a heat resistant and nonconductive material.

35. A method for interstitial treatment or diagnosis within an organ, comprising:

placing a tubular member within a body passage adjacent to the organ to be treated;

guiding a cannula with said tubular member and inserting the cannula into the organ by puncturing the tissue thereof, said cannula having a distal end and including means at the distal end for puncturing the tissue;

locating the distal end of the cannula at a treatment or diagnosis zone;

locking the cannula in the organ; and

performing the treatment or diagnosis at the zone.

36. The method according to claim 35, further comprising:

unlocking the cannula;

at least partially withdrawing the cannula;

reinserting the cannula to a second treatment or diagnosis zone;

locking the cannula; and

performing a further treatment or diagnosis.

37. The method according to claim 35, wherein said guiding and locating steps include:

inserting an endoscope into the tubular member;

viewing the direction of insertion through the endoscope;

determining the distance of insertion by observing contrasting markings spaced predetermined distances apart on the cannula; and

advancing the cannula with ultrasound imaging to a final position.

38. The method according to claim 35, wherein said locking step comprises moving a locking member disposed adjacent the distal end of the cannula from a first non-locking position to a second locking position extending into tissue surrounding the cannula.

39. The method according to claim 35, wherein:

the step of guiding and inserting the cannula includes placing a stylet in the cannula with a sharpened tip extending beyond the distal end and advancing the cannula and stylet together into the organ; and

the step of performing includes withdrawing the stylet, interstitially applying through the cannula a cell targeted compound sensitive to an energy type, and delivering said energy type through the cannula to the cells targeted by said compound.

40. The method according to claim 35, wherein said performing step includes sequentially performing one or more of delivering energy to the treatment zone, aspirating or irrigating the treatment zone, delivering drugs to the treatment zone, delivering radioactive material to the treatment zone, delivering a contrast material to the treatment zone, or locating an imaging device at the treatment zone.

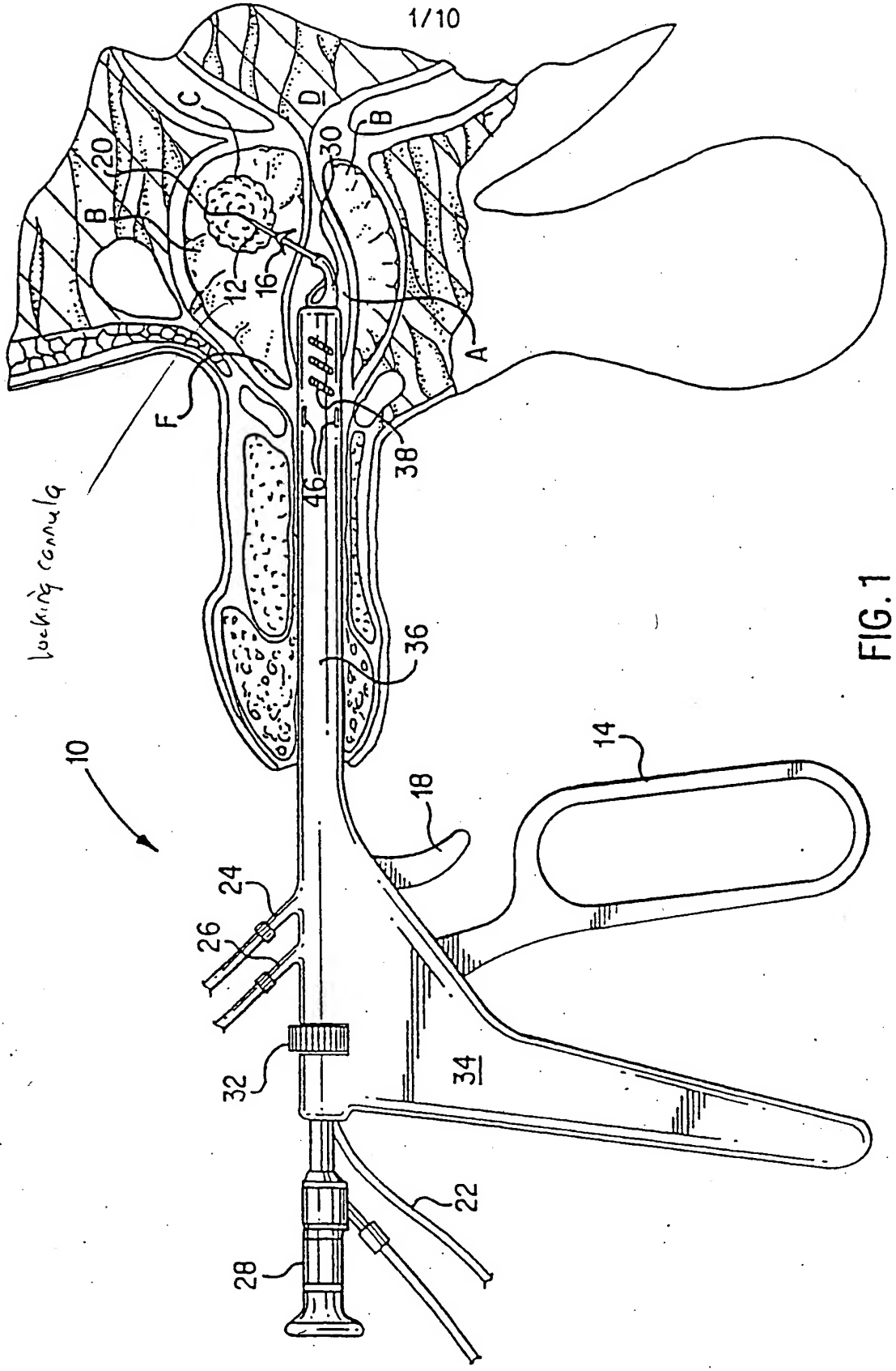
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FIG. 1

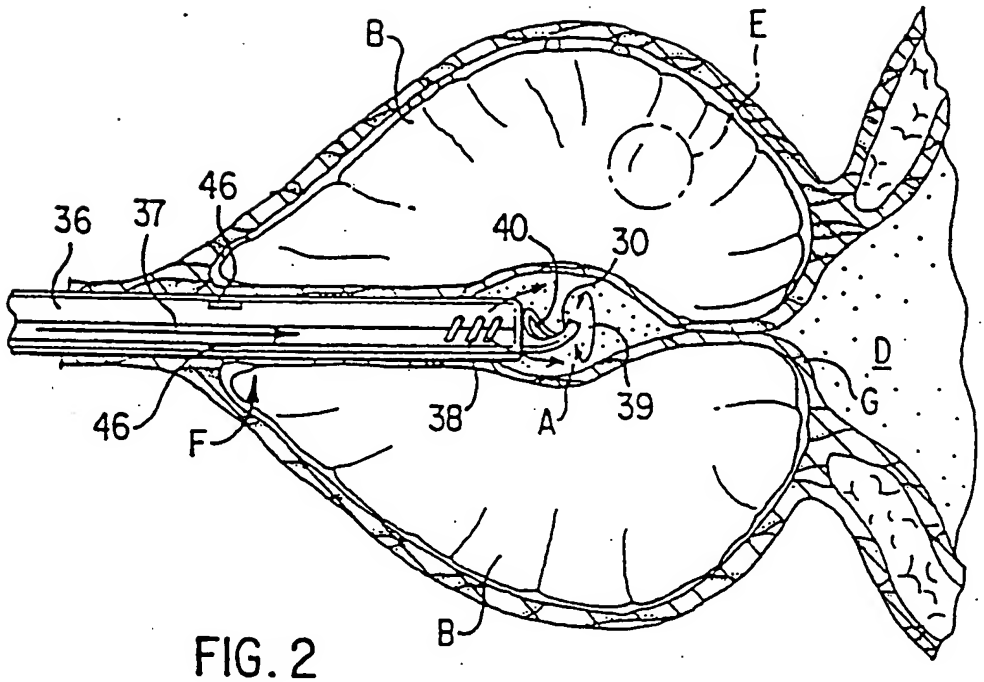

FIG. 2

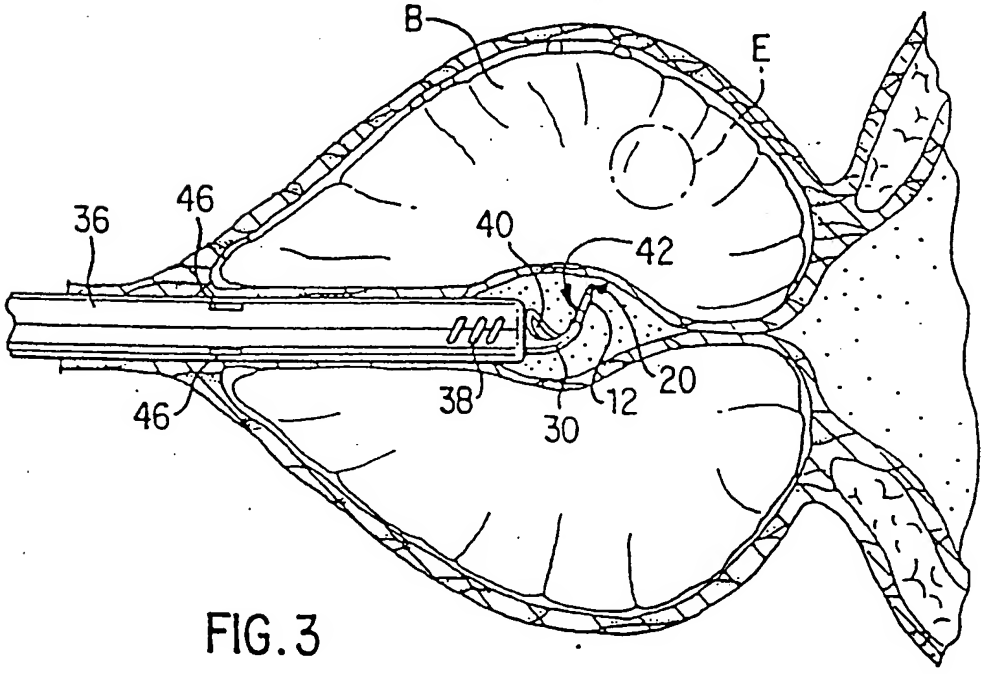

FIG. 3

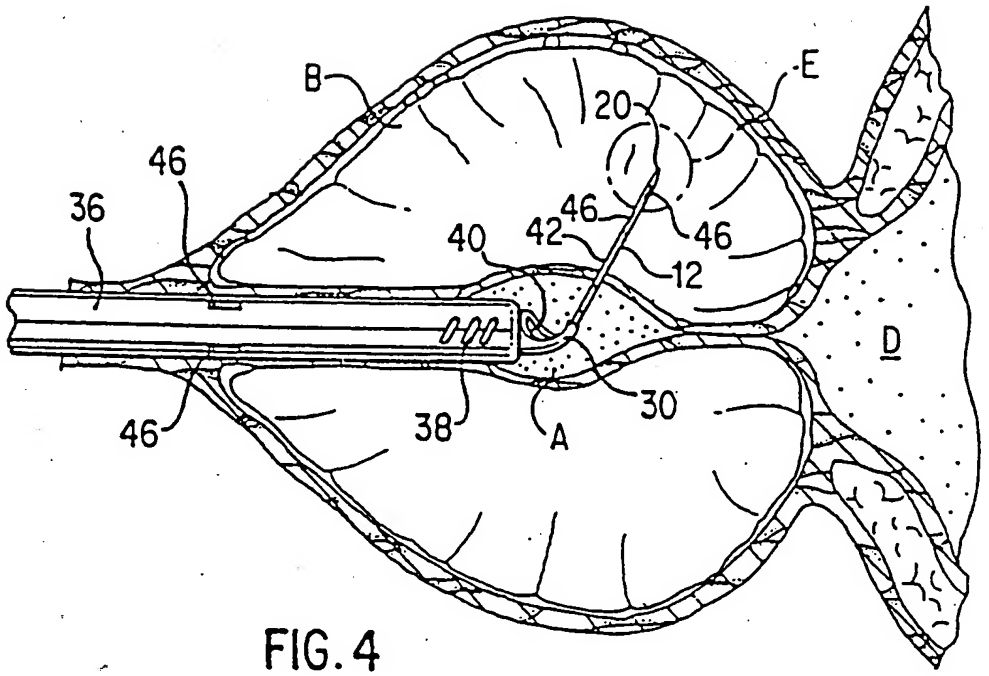
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FIG. 4

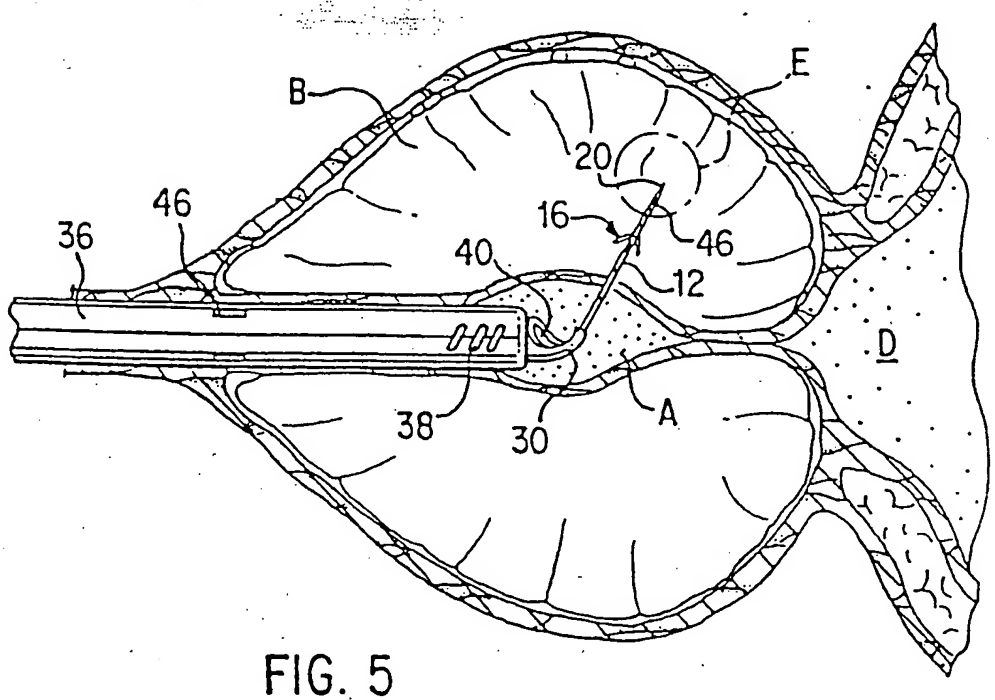
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FIG. 5

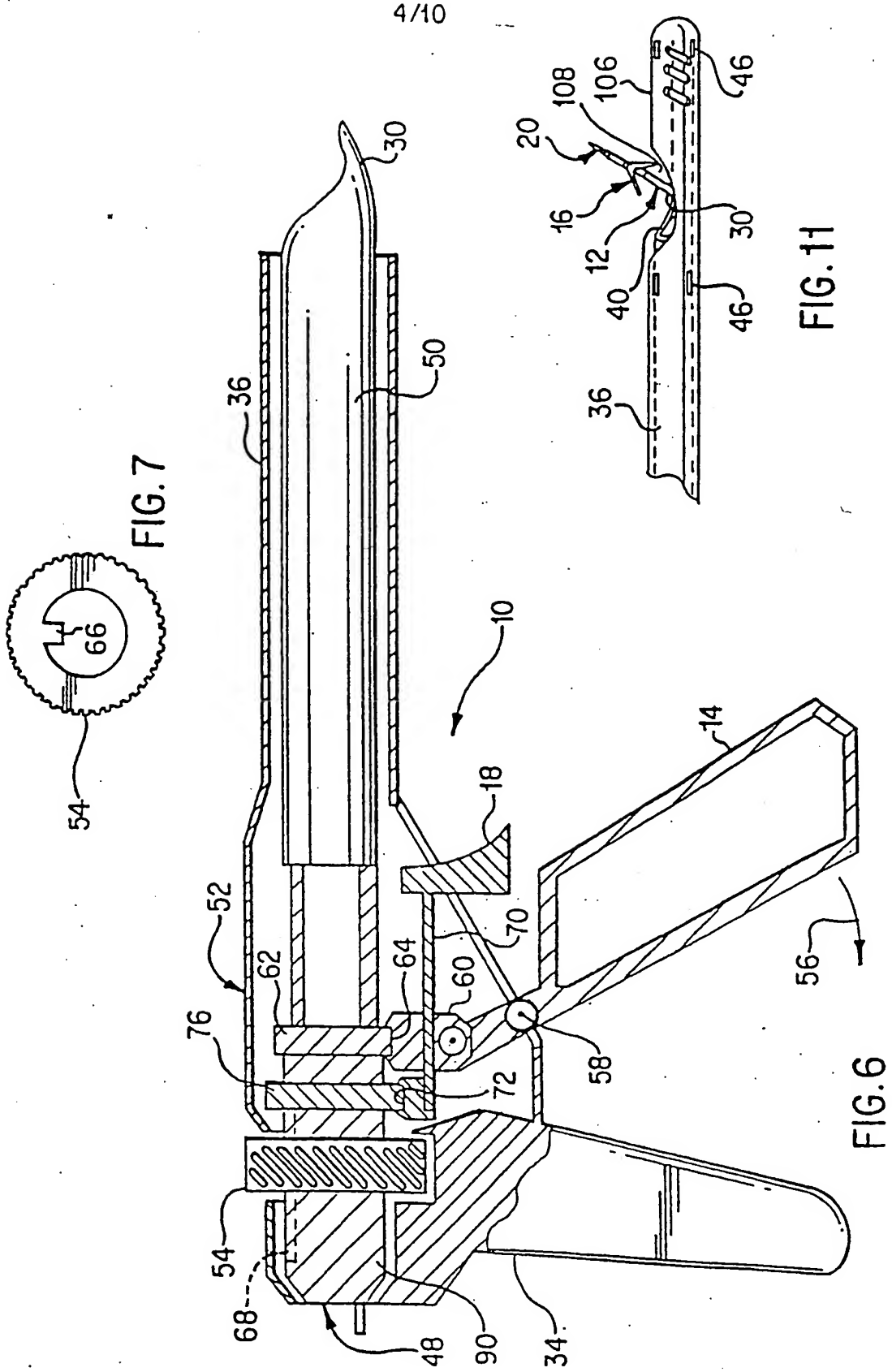

FIG. 7

FIG. 11

FIG. 6

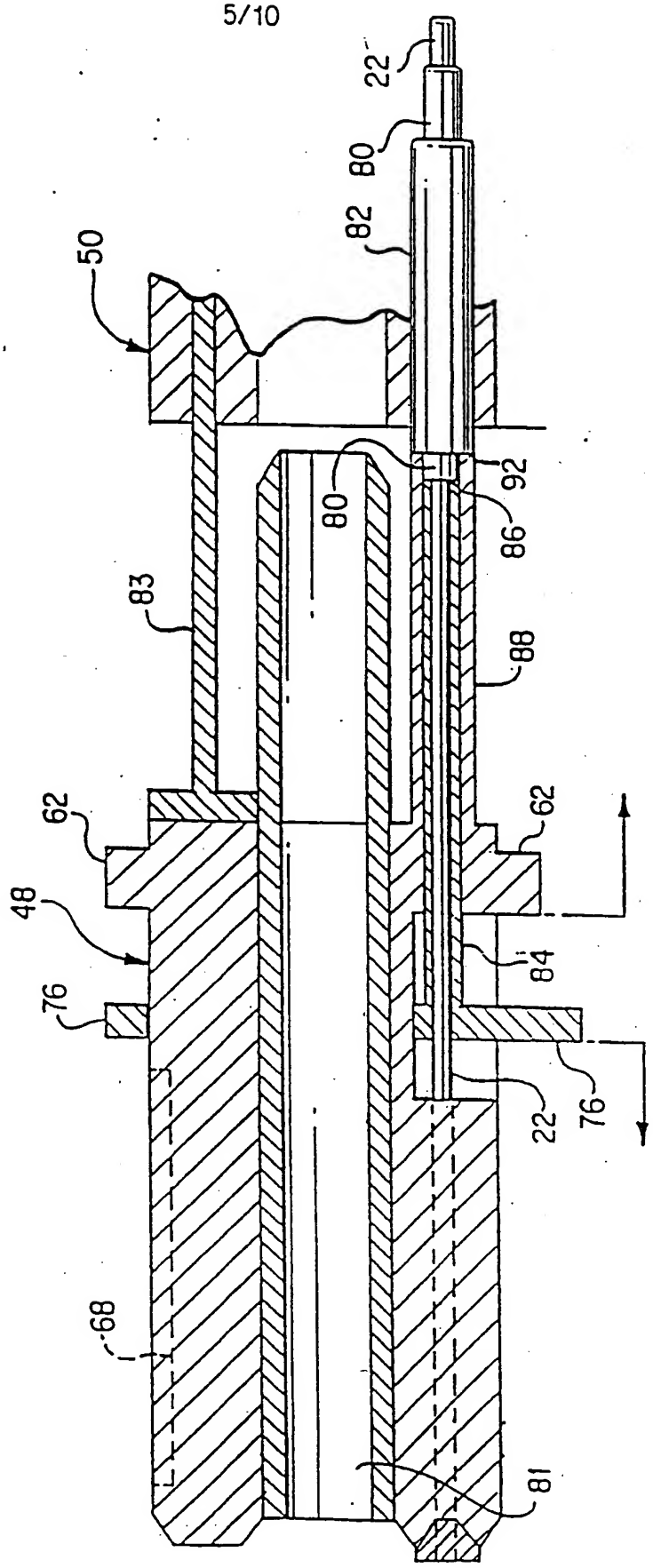

FIG. 8

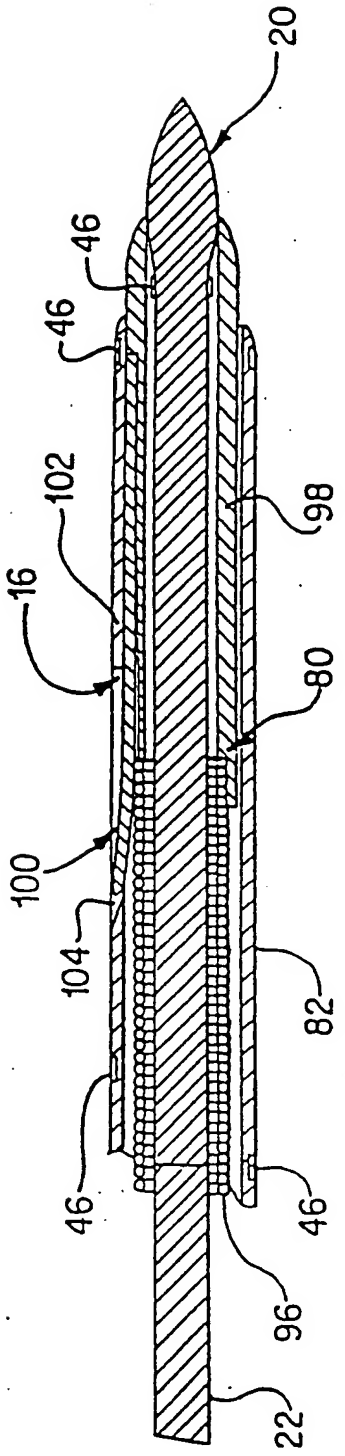
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FIG. 9

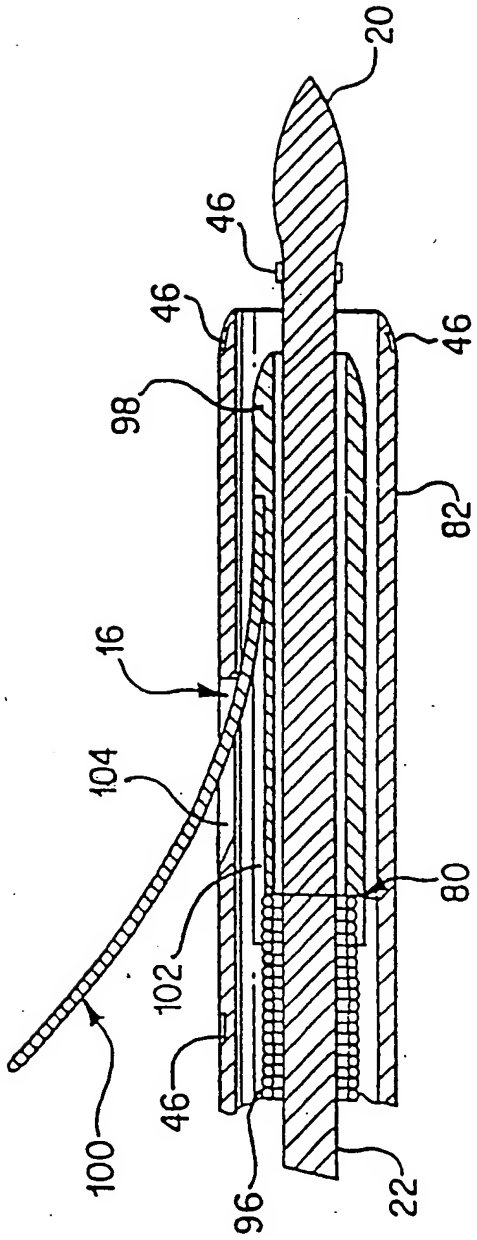
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FIG. 10

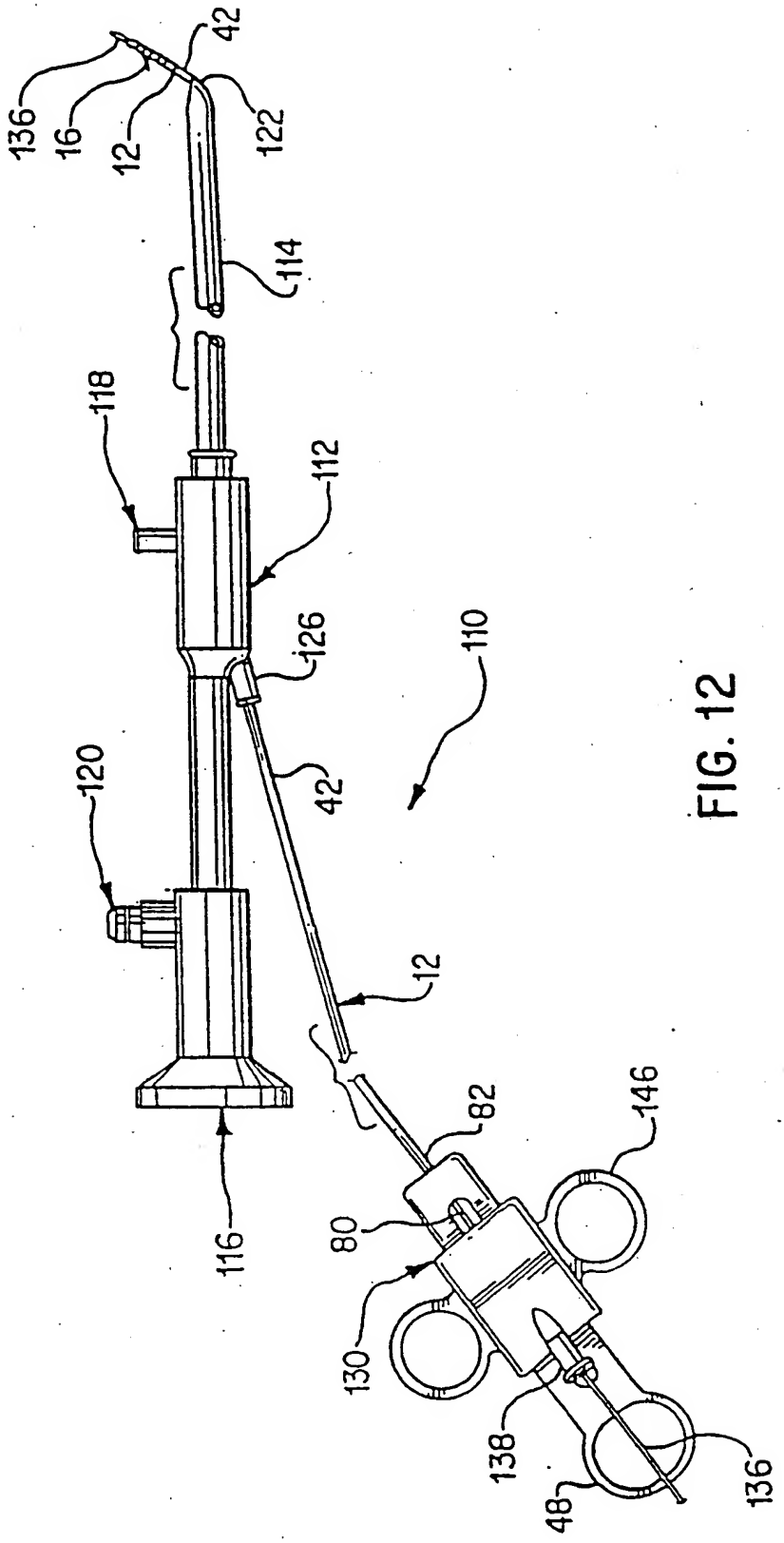
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FIG. 12

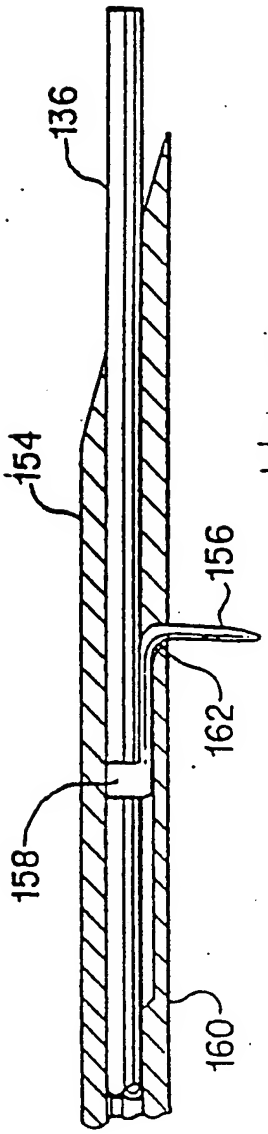

FIG. 19

FIG. 13

FIG. 14

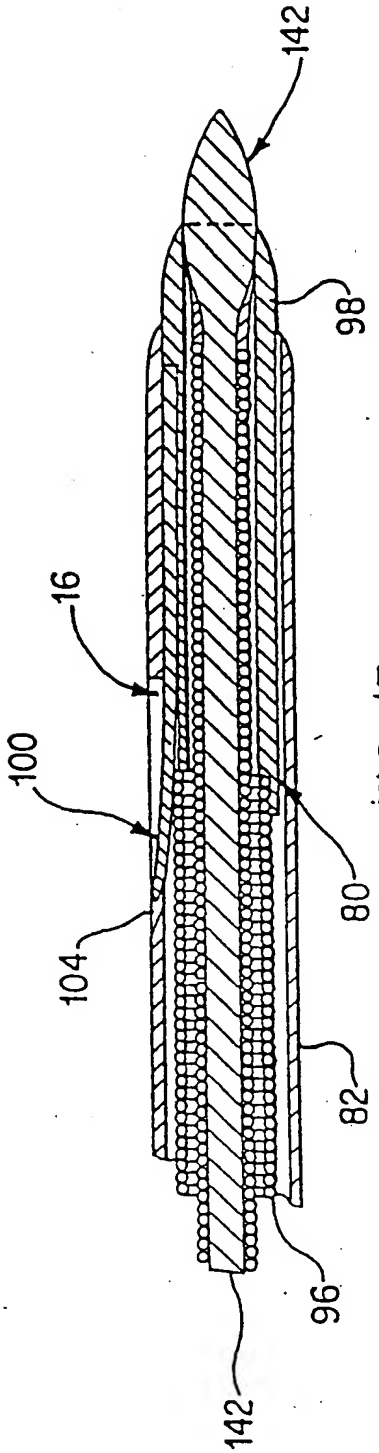

FIG. 15

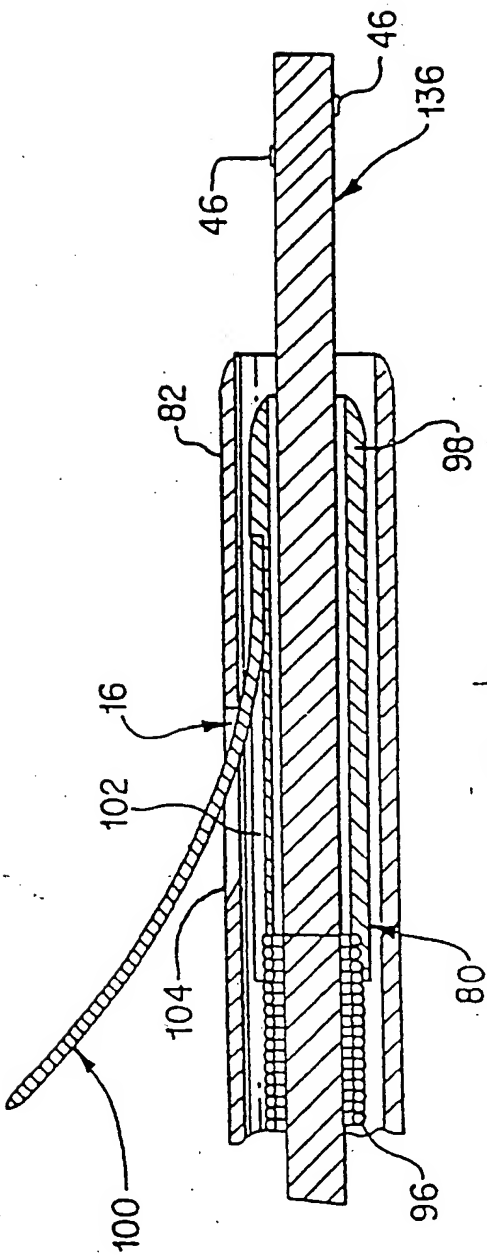

FIG. 16

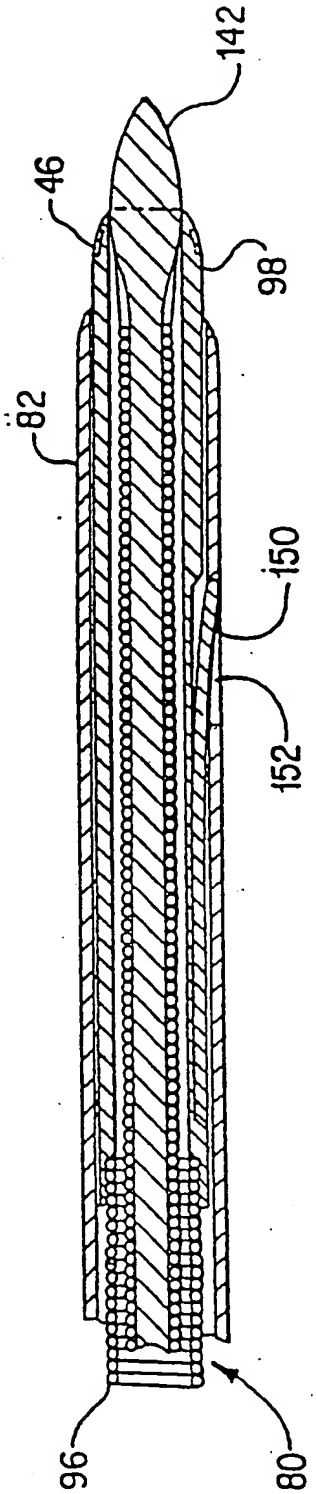

FIG. 17

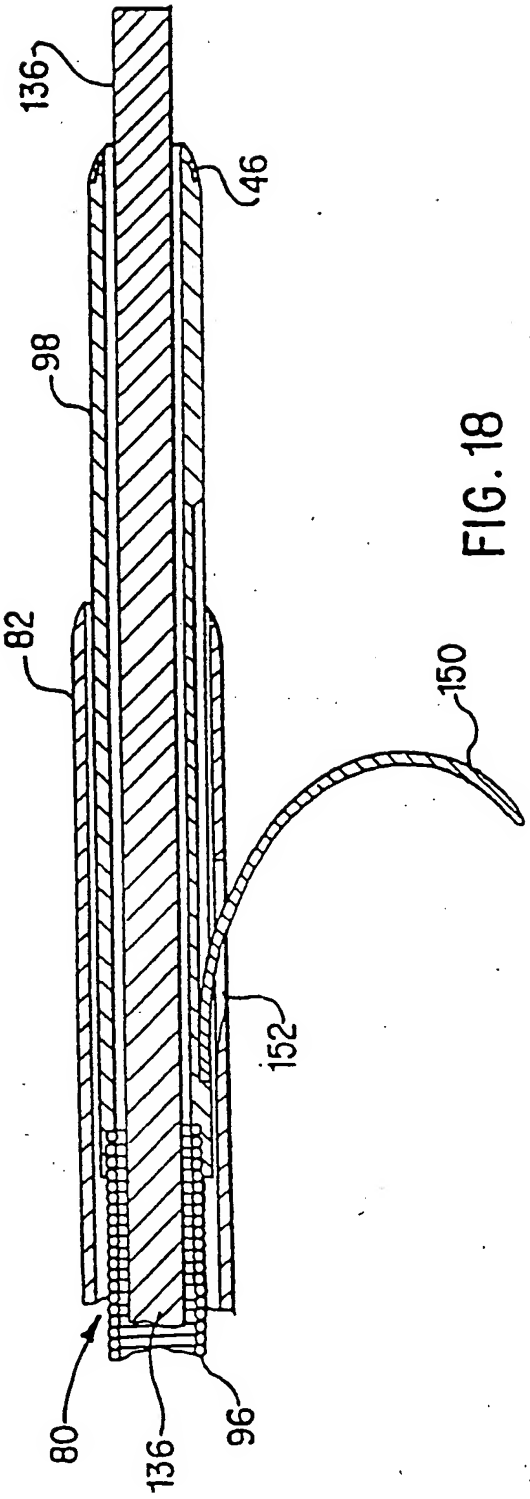

FIG. 18

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61B17/00; A61B17/36

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category *	Citation of Document,[11] with Indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
Y	US,A,4 545 374 (JACOBSON) 8 October 1985 see column 6, line 14 - line 19 see column 7, line 3 - line 13 see column 7, line 35 - line 39; figure 6 ---	1-34
Y	US,A,4 950 267 (ISHIHARA ET AL.) 21 August 1990 cited in the application see claims 1-9 ---	1-34
A	EP,A,0 385 604 (NATIONAL STANDARD COMPANY) 5 September 1990 see column 3, line 28 - line 47 see column 6, line 13 - line 17 --- -/--	4,8,11, 14,16, 23,30-32

* Special categories of cited documents :[10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
08 JUNE 1993	18.06.93
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	GLAS J.

ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. US 9301077
SA 70751

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 08/06/93

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-4545374	08-10-85	None	
US-A-4950267	21-08-90	JP-A- 1139081	31-05-89
EP-A-0385604	05-09-90	US-A- 4986279	22-01-91
		CA-A- 2002763	01-09-90
		JP-A- 2241446	26-09-90
US-A-4872456	10-10-89	None	
US-A-4803999	14-02-89	None	
US-A-4966597	30-10-90	None	
DE-A-3840749	07-06-90	None	
DE-C-640126		None	

EPO FORM P0479

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	US,A,4 872 456 (HASSON.) 10 October 1989 see column 3, line 34 - line 49	12,13, 20,24
A	US,A,4 803 999 (LIEGNER) 14 February 1989 see column 3, line 49 - line 51	25
A	US,A,4 966 597 (COSMAN) 30 October 1990 see column 3, line 61 - line 66	26
A	DE,A,3 840 749 (KOSCHER ET AL.) 7 June 1990	
A	DE,C,640 126 (LOEWEL) 24 December 1936	